AUG 0 2 2002

K022476

IV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ..... 3M ESPE

Street: ..... 3M Center Bldg 260-2B-12

City, State, Zip-code: ..... St. Paul, MN 55144

Country: ..... U.S.A

Establishment Registration Number: 2110898

Contact: ..... Karen O'Malley
Regulatory Affairs Specialist

Phone: 651 736-7326

Fax: 651 736-0990

E-mail: ..... kdomalley@mmm.com

Date of Submission: ..... July 24, 2002

Name of Device

Proprietary Name: ..... RelyX RMGIP

Classification Name: ..... Dental Cement

Common Name: ..... Luting Cement

Predicate Device:

RelyX Luting Cement ..... K 933139

GC FujiCEM..... K 001730

Description for the Premarket Notification

RelyX RMGIP is classified as a Dental Cement (21 C.F.R. § 872.3275) because it is a base cement used to affix dental devices such as crowns or bridges.

3M ESPE is submitting this Special 510(k) for modifications to RelyX Luting Cement. The modifications of RelyX Luting Cement concern minor changes of the chemical composition, however, the basic chemical design remains the same. The change is primarily the physical form of the delivered product and the means to dispense the product for placement in the dental procedure. A summary of the design change is:

- Paste/ paste delivery system for ease of mixing and delivery as compared to existing powder/ liquid systems.
- Consistent cement properties because of exact mixing ratio
- Less preparation and clean-up steps

RelyX RMGIP is designed to retain the excellent physical, mechanical and clinical properties of existing RelyX Luting Cement. Like RelyX Luting Cement and GC FujiCEM, RelyX RMGIP has the same basic chemical composition and material characteristics for patient application. RelyX RMGIP cement is a self-curing, radiopaque, fluoride-releasing, resin-modified glass ionomer luting cement. The cement consists of a base and catalyst paste packaged in the 3M ESPE Clicker dispensing system. RelyX RMGIP is available in a white shade.

The modified luting cement, RelyX RMGIP, has the following similarities to the currently marketed RelyX Luting Cement:

- Both cements have the same intended use.
- Both are resin modified glass ionomer cements incorporating the same major chemical components.
- Both cements have the same shelf life and storage conditions.

To provide evidence for safety, the chemical composition of RelyX RMGIP was compared to RelyX Luting Cement. Additionally, independent research institutes carried out biocompatibility testing. The results show that RelyX RMGIP is a safe device when used as directed.

To demonstrate the effectiveness of RelyX RMGIP, the performance characteristics of RelyX RMGIP were compared to RelyX Luting Cement and GC FujiCEM.

In summary, the modified dental cement, RelyX RMGIP, described in this Special 510(k) pre-market notification submission is substantially equivalent to the predicate device. This is our position with regard to intended use, major chemical components, shelf life, storage conditions, safety and effectiveness,.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 02 2002

Ms. Karen O'Malley
Regulatory Affairs Specialist
3M ESPE
3M Center Building 260-2B-12
Saint Paul, Minnesota 55144

Re: K022476
Trade/Device Name: RelyX RMGIP
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: July 24, 2002
Received: July 29, 2002

Dear Ms. O'Malley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cucinotta for

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

(As Required by 21 C.F.R. § 801.109)

510(k) Number: K022476

Device Name: RelyX RMGIP

Indications for use:

Luting porcelain fused to metal crowns and bridges to tooth structure, amalgam, composite or glass ionomer core build ups;

Luting metal inlays, onlays or crowns;

Luting pre-fabricated and cast post cementation

Luting orthodontic appliances

Luting crowns made with all-alumina or all-zirconia cores such as Procera® AllCeram

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022476

Prescription use: ☑ Over the counter use: ☐